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13. ABSTRACT (Maximum 200 Words)

The research objective of this 4-year study is to evaluate the effectiveness of a minimal contact Internet-based behavioral therapy plus usual care (MCBT + UC) for controlling overweight in USAF personnel using a controlled experimental comparison of usual care (UC). Subjects include personnel who are 5 lbs below their Maximum Allowable Weight (MAW) and heavier. Effectiveness of MCBT + UC is compared to UC in terms of weight loss. Outcomes are being measured at 6 and 12 months.

Recruitment ended in October 2004 with a total of 451 subjects (227 in treatment group and 224 in usual care group). Both groups include approximately 50% men and women and an ethnic representation of 55% Caucasian, 23% African American, 16% Hispanic, 6% all others (Asian, Pacific Islander, Other). Mean age for subjects is 33.9 years and body mass index, 29.4. To date, 215 subjects (94.7%) have completed the treatment program. All follow-up assessments will be completed by October 2005. Preliminary results comparing baseline and 6-month outcome found that subjects assigned to MCBT lost weight while those assigned to UC actually gained weight. Also, greater use of the treatment website was associated with significantly more weight loss over the 6 month treatment period.

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INTRODUCTION:

Maintaining healthy body weight is a critical part of readiness in the United States Air Force (USAF). The USAF has not escaped the same weight management problems that the US civilian population is experiencing. Therefore, the need for improving existing weight programs currently available to the USAF is of great importance and part of the mission of this study. The research objective of this study is to evaluate the effectiveness of a minimal contact behavioral therapy plus usual care (MCBT + UC) for controlling overweight in the USAF personnel using a controlled experimental comparison of usual care (UC). Subjects include active duty personnel who are 5 lbs. below their Maximum Allowable Weight (MAW) and heavier. Effectiveness of MCBT + UC will be compared to UC in terms of weight loss. Outcomes are measured at 6 and 12 months. The ultimate goal of this study is to provide an effective and easily disseminable weight management treatment to any interested military installation.

BODY:

A request for a no-cost extension and a revised Statement of Work (Appendix 1) was submitted in February 2005 and was approved in April 2005. Our performance period for research has been extended until 14 April 2006; therefore, this report is an annual report for Year 3.

The following tasks have been accomplished in months 25 to 36 of the grant period (as outlined in the revised and approved Statement of Work):

YEAR 3 (15 April 2004 – 14 April 2005):

1) Began 12-month follow up assessments for individuals in both conditions (MCBT+UC & UC) – Month 26

Twelve-month follow up assessments began in June 2004 (month 26). They are conducted on a weekly basis and are on target to be completed by October 2005.

2) Continued orientation, assessment, data management, and treatment related activities

The final orientation session for the study's treatment program was conducted in November 2004. Online diary submissions by subjects in treatment condition and staff review are on target to end in April 2005. Six-month follow up assessments continue to be conducted on a weekly basis and are on schedule to be completed by June 2005.

3) Recruitment ended at the three HAWC sites in October 2004. Total number of participants recruited: 451.

The total number of participants recruited is less than the number proposed in the original protocol. Prior to a report of statistical results, the difficulties in accomplishing our recruitment are discussed.

In January 2004, a new official Air Force policy regarding weight and fitness was implemented (Air Force Instruction- AFI 10-248, Fitness Program). These changes in Air Force policy caused severe disruptions and substantial delays in our recruitment of study participants. This new policy impacted our recruitment in two significant ways: the elimination of a mandatory Maximum Allowable Weight (MAW) for Active Duty personnel and the elimination of the position of Fitness Assessment Monitor (FAM), our primary means of recruitment.

Study recruitment began in June 2003 using inclusion criteria based on MAWs. In January 2004, the new AFI regulations eliminated MAWs, no longer requiring Active Duty personnel to maintain a specific weight based on their height. However, weight remains an important issue as abdominal circumference was added as a dimension of the new required annual fitness exam. Our inclusion criteria for height/ weight remained the same following the AFI change in January 2004; however, recruitment materials were altered to emphasize reduction of abdominal circumference through weight loss and any references to MAWs were removed. Testing for the new annual fitness exam did not begin until March 2004. Recruitment for our study decreased dramatically during the time the bases were essentially "in limbo" as they transitioned from one program to the other (September 03 and March 04). Even with the new emphasis on abdominal circumference, there appeared to be a decrease overall in motivation for weight loss once the

MAWs were eliminated. Eventually, recruitment increased once the new fitness exam was being conducted on a regular basis and penalties for failing the exam were implemented. Penalties include mandatory attendance of health and fitness classes as well as more frequent re-testing. We were allowed to brief these classes on our study and increase recruitment.

This study focused on recruiting individuals over their MAW for weight loss, and those who were close to their MAW (within 5 lbs below their MAW) to prevent weight gain. It was estimated in the original protocol that 600 subjects would be recruited for the above MAW group and 600 for the below MAW group. Enrollment of individuals in the below MAW group proved extremely difficult. Despite equal efforts in recruitment, we were unable to successfully recruit the proposed number of individuals for the below MAW group. Individuals who were close to, but below their MAW were not subject to any official penalties by the Air Force and their motivation to join a weight gain prevention study appears to have been greatly overestimated. With the elimination of the MAW requirement in January 2004, recruitment of individuals for the below MAW group decreased even further. Only 12.6% of study participants are in the below MAW category, not the 50% that was estimated in the original protocol. In the end, we recruited 394 subjects for the above MAW group and 57 subjects for the below MAW group. We will no longer be able to investigate our secondary hypotheses comparing the subgroups due to the insufficient recruitment of the below MAW group. However, we will be able to answer our primary hypothesis comparing the 2 treatments (MCBT + UC and UC) with respect to weight loss from baseline to the one-year follow-up. Power is sufficient to answer this research aim. Also, for the purposes of this report, we have included statistical results stratified by MAW status.

Our recruitment efforts were further influenced by the elimination of the position of Fitness Assessment Monitor (FAM) in the new AF policy. The FAMs at the 3 recruitment sites provided us with our primary means of communication with Active Duty personnel. The FAMs administered the required annual ergometry testing and assisted us by identifying potential subjects based on their MAW. In anticipation of the new AFI regulations in January 2004, regular ergometry testing at all 3 bases was discontinued in September 2003. This effectively halted our primary means of communication with Active Duty personnel through the FAMs. We were then required to find other methods of recruitment. As discussed in our second annual report, these methods focused on the development and distribution of informational flyers used in both an electronic and paper format. There was a significant delay in distributing these flyers as it took more than 6 weeks to receive approval from the 4 required IRBs. These flyers were distributed at numerous briefings and at locations frequented by Active Duty personnel such as fitness centers.

The new AFI policy created a position similar to the FAM called the Physical Training Leader (PTL), but these individuals were not appointed or trained until late January 2004 and testing of Active Duty personnel did not begin until March 2004. Our research staff took part in each weekly training session for new PTLs from late January to mid October 2004. We asked the PTLs for their assistance in distributing information about our study to individuals who failed to meet the abdominal circumference requirements of the new fitness exam. The PTLs eventually became a regular source of referrals for our study.

These changes in Air Force policy could not have been foreseen or prevented by our research group. Regular ergometry testing and availability of FAMs ended after only 4 months of recruitment and with no advance notice to the researchers. The new AFI regulations were not made available for distribution and evaluation by researchers until January 2004. This caused

significant delays in our recruitment and required increased effort by research staff in terms of recruitment activities and availability to perform assessments. In addition to the weekly PTL trainings, staff took part in monthly briefings of Air Force groups that could aid in recruitment at all 3 bases. Such groups included First Sergeants meetings, Newcomer's Orientations, and Primary Care staff meetings at clinics. Staff members also attended all weekly classes that were required for individuals who did not meet fitness standards. These included Healthy Living Workshops, Fitness Improvement Program classes, and Body Composition Improvement Program classes. Staff members also made multiple visits to each base weekly for assessments to accommodate schedules of the recruitment sites and Active Duty personnel. We also wanted to ensure recruitment was continuous at all 3 bases. Multiple weekly visits continue at Randolph and Lackland AFBs as follow-ups are still being conducted. The original protocol outlined only one weekly visit to each base for study assessments and made no allowance for visits related to recruitment. Funding was carefully budgeted to allow for multiple site visits each week and extended employment of staff through October 2005 for completion of follow-up assessments.

It is also important to note the effects of the war-fighting mission of the Air Force on recruitment and follow-up assessments. Overall support of this study has remained relatively stable at all 3 bases; however, duty reassignments due to mobilization for war caused numerous staff changes at all HAWC recruitments/assessment sites. Staff members at the HAWC were crucial for us in terms of support as they supervised and communicated regularly with all FAMs. They also helped distribute study information such as flyers to Active Duty personnel who frequented the HAWC. In addition to staff changes, there was also a necessary redirection of support and energy to the war-fighting mission. We briefed all new staff members on the study and recruitment criteria, but we were also required to increase research staff presence at these locations to maintain awareness and support of our study. The HAWC recruitment sites became one of the sites for mandatory pre-deployment briefings, and we are often limited in available time and space for our assessments. This was especially true for our baseline assessments. The full impact of duty reassignments on attendance for follow-up assessments has yet to be determined as 6- and 12-month follow-ups are still underway. However, deployment is listed as one of the most common reasons that our subjects are unable to attend their follow-up assessments.

Changes in Air Force mission and policy played a major role in recruitment difficulties. However, we also experienced problems enrolling subjects at one recruitment site in particular. It was initially projected that we would recruit approximately 30% of participants from Brooks City Base. Only 4% of study participants were recruited from this site despite equal effort given in terms of recruitment briefings, etc. Initial projections overestimated our recruitment potential at this site. Brooks City Base has the smallest population of Active Duty personnel of the 3 recruitment sites.

An additional 236 contacts with potential subjects were made during the recruitment phase of this study. These contacts included 151 individuals who were screened, but were ineligible based on study criteria. Contacts and other reasons for non-participation are outlined in Table 1.

Table 1. Potential subject contacts during recruitment phase

Ineligible screenings	
Not Active Duty Air Force	11
Leaving local area within year	33
Did not meet height/weight requirements	37
Lost more than 10 lbs in last 3 months	20
Pregnancy issues (e.g., planning pregnancy, breastfeeding)	12
Medical issues (e.g., thyroid difficulties, diabetes)	38
Miscellaneous	
No longer interested in participating after receiving program description	35
Screened, eligible, but never attended baseline session	31
Completed Permission to Contact form, but unreachable for eligibility screening	19
TOTAL	236

Despite the above difficulties in recruitment, we have very low attrition rates for this type of research (19%) and one of the largest samples ever evaluated in a randomized controlled trial (RCT) of an applied weight loss program. Further, this is the largest RCT, to date, of an interactive Internet weight loss program.

Results

Follow-up assessments are currently in progress. It is important to note that the following report of results and significance includes preliminary findings as only approximately 80% of 6-month follow-ups have been completed to date. Sufficient 12-month data has not been collected at this time to allow for meaningful analysis.

Participants

A total of 227 participants were randomized to receive the MCBT weight loss intervention and 224 to usual care. Both groups include approximately 50% men and women and an ethnic representation of 55% Caucasian, 23% African American, 16% Hispanic, 6% all others (Asian, Pacific Islander, Other). Our study population is more diverse than the ethnic representation of the USAF; however, we consider this to be beneficial, as minorities have been greatly underrepresented in clinical settings. Mean age for subjects is 33.9 years and body mass index, 29.4.

There were no significant differences in the distribution of demographic factors or clinical variables between participants in the treatment or usual care groups. Baseline participant characteristics, stratified by MAW status, are presented in Table 2.

Table 2. Participant Characteristics by MAW Status

Characteristic*	Treatment	Usual Care	p-value
Above MAW			
N	201	193	
Age (yrs)	33.7±7.4	34.4±6.9	0.362
Gender (% Female)	51.2	50.3	0.845
Ethnicity (% Caucasian)	56.7	53.4	0.897
Marital Status (% Married or partnered)	71.6	72.5	0.775
Percent Enlisted (%)	81.2	77.7	0.939
Years of Service (yrs)	12.7±6.5	13.1±6.3	0.523
Plan to retire from AF (% yes)	78.5	83.8	0.408
Education (% at least HS)	64.2	64.8	0.826
BMI (kg/m^2)	29.9±2.9	29.9±2.8	0.979
Weight (kg)	88.5±15.7	88.3±14.5	0.901
% Obese (BMI≥30)	40.3	46.6	0.205
Waist Circumference (in)	37.4±4.3	37.4±5.0	0.841
Body Fat (%)	35.3±6.6	35.0±6.7	0.225
Est. VO2Max (mL.kg.min)	14.3±16.8	12.0±16.4	0.715
Below MAW			
N	26	31	
Age (yrs)	30.9±7.1	34.0±9.4	0.176
Gender (% Female)	46.2	54.8	0.514
Ethnicity (% Caucasian)	65.4	51.6	0.115
Marital Status (% Married or partnered)	57.7	74.2	0.271
Percent Enlisted (%)	84.6	61.3	0.380
Years of Service (yrs)	9.2±6.8	11.8±7.9	0.200
Plan to retire from AF (% yes)	76.9	64.5	0.532
Education (% at least HS)	11.5	6.5	0.492
BMI (kg/m^2)	26.3±1.4	26.0±1.4	0.487
Weight (kg)	78.1±11.4	75.5±10.6	0.380
% Obese (BMI>30)	0.0	0.0	--
Waist Circumference (in)	34.4±4.3	37.2±4.9	0.348
Body Fat (%)	29.5±6.5	29.7±6.1	0.933
Est. VO2Max (mL.kg.min)	17.4±16.6	8.0±14.6	0.071

*No statistically significant differences between groups

Intervention Fidelity Check

We first examined several process variables to ensure that MCBT was delivered to participants assigned to the treatment group. First, we calculated the frequency of receiving the motivational phone calls during the treatment period and found that 93.4% of treated participants were available for the 4-week motivational phone call and 78.4% received the 8-week call. Next, we examined website use by participant self-report and total actual website logins. Participants reported their website use as less than once per week (42.4%), 1-2 (22.6%), 3-4 (18.1%), 5-7 (9.6%), and 7+ (7.3%) times per week, respectively. Treated participants logged into the website an average of 49.1(83.3) times over the treatment period, with a range of 1-707 logins. We then converted the actual logins into quartiles of use and found the following distribution of total logins: Quartile 1 = 17.5%; Quartile 2 = 24.1%; Quartile 3 = 27.1%; and Quartile 4 = 31.31%.

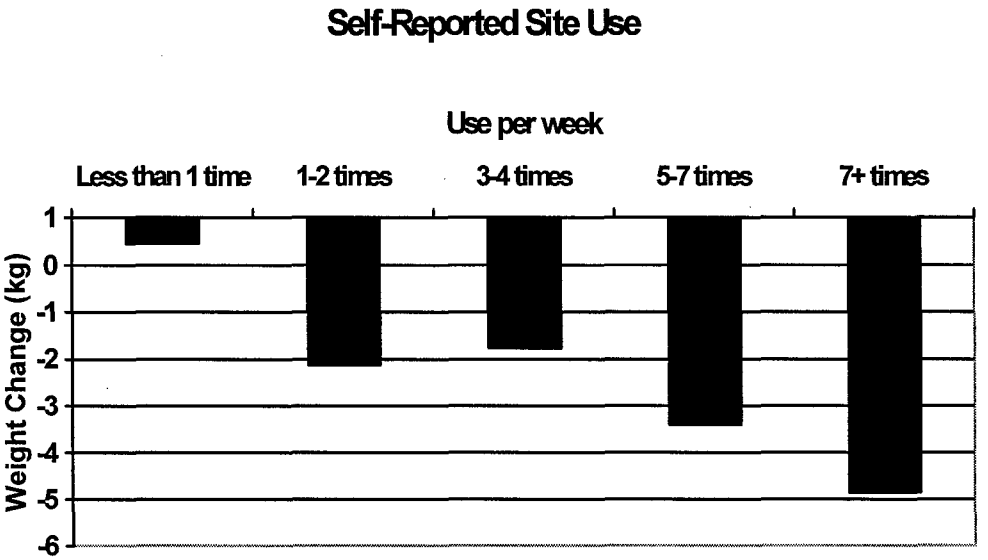
We examined the relationship between weight loss and self-reported website use and actual logins. Table 3 presents the correlations and significance levels.

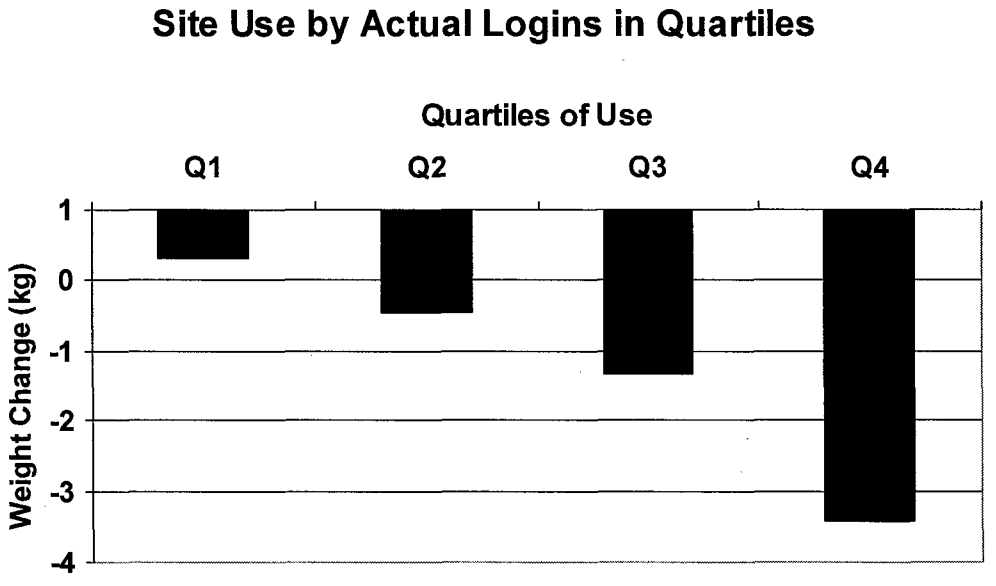
Table 3. Intervention Fidelity Check Among Treated Participants

	Number of Logins From Site Counter	Self-Reported Logins
6 Month Weight Change	**-0.391(<0.001)**	**-0.394(<0.001)**
Self-Reported Logins	**0.559(<0.001)**	**--**

There was a significant and modest relationship between both self-reported website use, actual login frequency, and weight loss, indicating that greater use of the website by either metric was associated with significantly more weight loss over the 6 month treatment period. In addition, Figure 1 presents weight losses (kg) by category of self-reported use and by actual login quartile. Treated participants generally lost more weight with greater use of the site regardless of metric (i.e., self-reported weekly use or total actual logins).

Figure 1. Weight Change by Category of Self-Reported Website Use and Site Logins





Changes in Body Composition

Table 4 presents changes in body composition by treatment assignment stratified by MAW status.

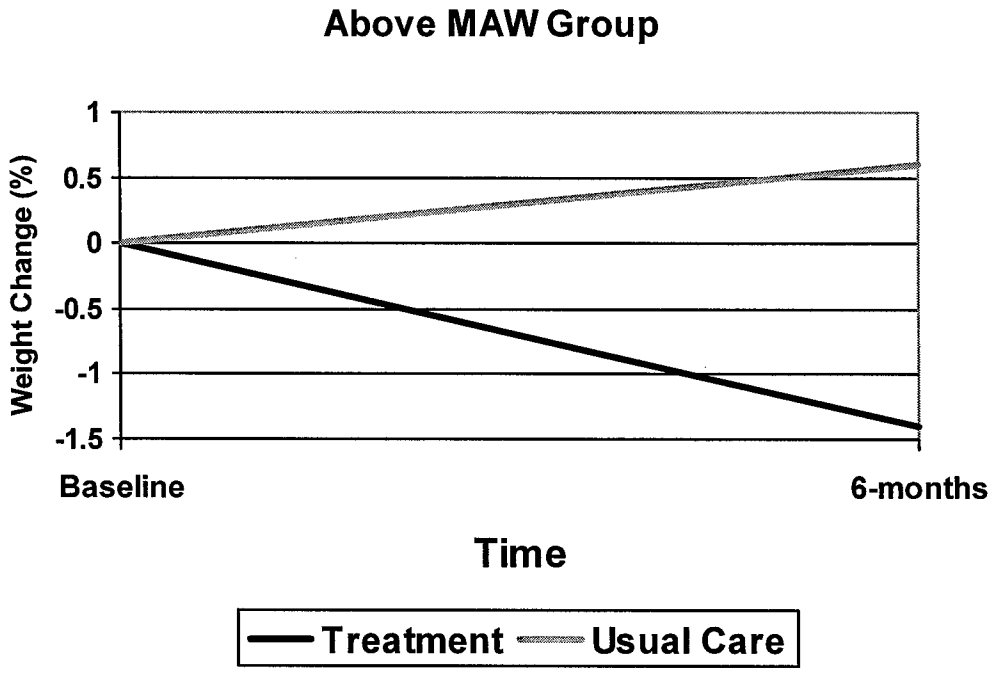
Table 4. Primary Outcomes from Baseline to 6-month Outcome

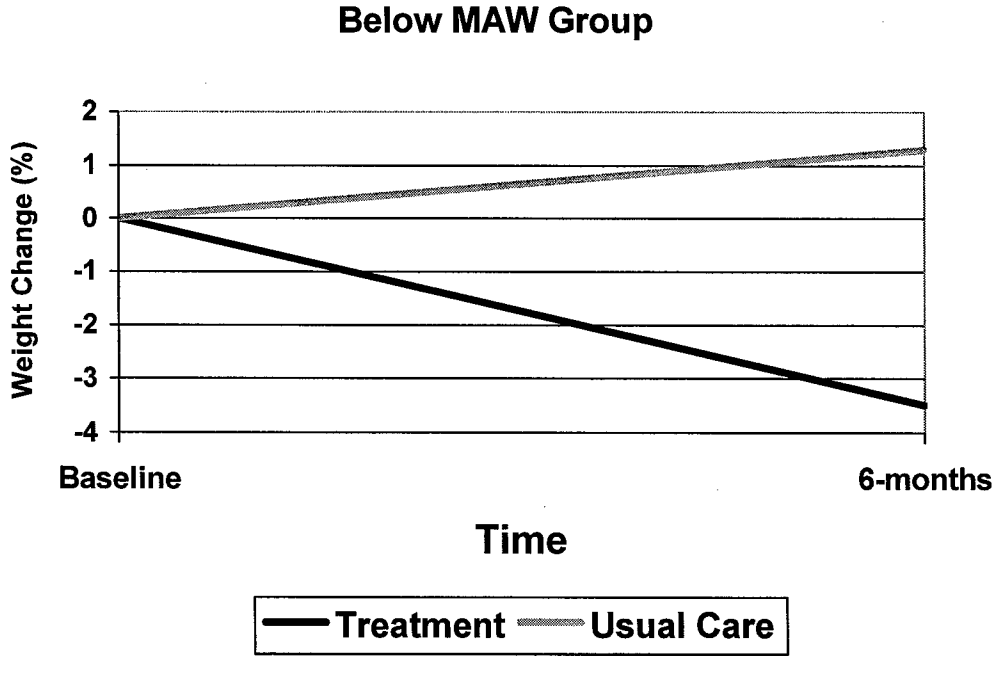
Outcomes	Treatment	Usual Care
	Above MAW	
Weight (kg)	-1.2±4.0	0.5±3.5
BMI (kg/m^2)	-0.4±1.4	0.2±1.2
Waist Circumference (cm)	-2.0±4.2	-0.5±3.9
Bodyfat Percentage	-0.4±3.1	0.6±3.0
5% or More Weight Change (% yes)	23.2	7.4
No follow-up - 6 months (% dropout)	22.9	15.5
	Below MAW	
Weight (kg)	-2.7±4.4	1.0±2.3
BMI (kg/m^2)	-0.9±1.5	0.3±0.8
Waist Circumference (cm)	-2.9±5.1	0.5±2.8
Bodyfat Percentage	-0.7±3.5	0.9±2.0
5% or More Weight Change (% yes)	20.0	4.0
No follow-up - 6 months (% dropout)	23.1	19.4

Participants assigned to MCBT who were above MAW lost -1.2±4.0kg while those assigned to usual care actually gained 0.5±3.5kg and this difference was statistically significant using RANOVA (Wilk's Lamda = 15.66; $p<0.001$). Results were even more dramatic for the Below MAW group, with participants who received the MCBT losing -2.7±4.4kg while those in usual care gained 1.0±2.3kg (Wilk's Lamda = 13.27; $p=0.001$). Changes in the other body composition outcomes, i.e., BMI, waist circumference, and body fat percentage also are presented in Table 4. Treated participants experienced significantly greater favorable body composition changes on all measures ($p<0.01$ for all) except for body fat in the below MAW group ($p=0.074$).

Significantly more treated participants met the 5% or more weight loss criterion, regardless of MAW status. Figure 2 presents weight loss (weight change percent) by treatment status. Among the above MAW group, 23.2% lost at least 5% of initial body weight compared to only 7.4% of usual care participants ($p<0.001$). Among below MAW participants, more treated (20.0%) than usual care (4.0%) met the criterion, but the difference was not significant ($p=0.090$), most likely due to the small number of individuals in the below MAW stratum. There were no significant differences in follow-up at 6 months across groups, with an overall attrition rate of 19.3% for the above MAW group and 21.1% for the below MAW group.

Figure 2. Weight loss (Weight Change Percent) by Treatment Status





KEY RESEARCH ACCOMPLISHMENTS:

- Recruitment was completed in October 2004. A total of 451 subjects were recruited (227 subjects were randomized to the treatment condition/MCBT and 224 to the usual care condition).
- A total of 363 six-month follow-ups have been completed to date. The 12-month follow-up assessments are underway and are on schedule to be completed by October 2005.
- 215 subjects have completed 6-month treatment program at the time of this report.
- Participants in treatment group have logged into the website an average of 49.1(83.3) times over the treatment period, with a range of 1-707 logins.
- 93.4% completion rate for 4-week and 78.4% completion rate for 8-week Motivational Interview phone calls for treatment subjects.
- Preliminary results comparing baseline and 6-month outcome found that, regardless of MAW status, participants assigned to the MCBT lost weight while those assigned to usual care actually gained weight.
- There was also a significant and modest relationship between both self-reported website use, actual login frequency, and weight loss, indicating that greater use of the website by either metric was associated with significantly more weight loss over the 6 month treatment period.

REPORTABLE OUTCOMES:

This study was presented at a national conference by associate investigator, Maj Christine Hunter, Ph.D.:

Hunter, C. Weight Management Issues in the Military. Invited presentation to the North American Association for the Study of Obesity (NAASO) Annual Scientific Meeting. Presentation, Las Vegas, Nevada, November 14-18, 2004.

CONCLUSIONS:

Changes in Air Force mission and policy played a major role in recruitment difficulties for this study. These changes could not have been foreseen or prevented by our research group. Despite these difficulties, this study remains scientifically viable and within compliance for the deliverables in the approved, revised Statement of Work. The one-year, no-cost extension will allow for completion of follow-up assessments and data analysis. Funding was carefully budgeted to allow for extended employment of staff to expand recruitment and to complete all follow-up assessments.

Preliminary results comparing baseline and 6-month outcome found that participants assigned to MCBT treatment condition lost weight while those assigned to usual care actually gained weight. Greater use of the treatment website was also associated with significantly more weight loss over the 6 month treatment period. These results, while preliminary, are encouraging. The potential efficacy of such a state-of-the-art approach as the Internet for weight loss has important implications for both a military and civilian population. Given the stigma of excess weight in the military along with a high operational tempo, the efficacy of minimal contact/flexible interventions is particularly important.

Despite our difficulties in recruitment, we have very low attrition rates for this type of research (19%). It is also important to note that this study has recruited one of the largest samples ever evaluated in a randomized controlled trial (RCT) of an applied weight loss program. Further, this is the largest RCT, to date, of an interactive Internet weight loss program.

REFERENCES:

Air Force Instruction- AFI 10-248, *Fitness Program*

APPENDIX 1:

The revised Statement of Work submitted in February 2005 and approved April 2005. Our performance period for research has now been extended until 14 April 2006.

Statement Of Work

1) The research objective of this study is to compare the effectiveness of a minimal contact behavioral therapy plus usual care (MCBT + UC) using a controlled experimental comparison of usual care (UC). Participants will include personnel who are 5 lbs below their former Maximum Allowable Weight (MAW) and heavier. Effectiveness of MCBT + UC will also be compared to UC in terms of percentage of participants who are below their former MAW. Outcomes will be measured at 6 and 12 months.

2) The project is designed to achieve the following technical objectives:

a) Create a minimal contact behavioral weight management program package that is specifically tailored to the military population, to include a treatment handbook for health care personnel, and a self-help guide and interactive behavior therapy Internet resource. The ultimate goal will be to provide an easily disseminated treatment package to any interested military installation.

b) Conduct a randomized trial to evaluate the efficacy of a minimal-contact population health approach to reducing the prevalence of overweight among military personnel by weight loss and prevention of weight gain. The project will employ proactive recruitment, an evidenced-based self-help book an Internet behavior therapy intervention, and motivational interviewing, as compared to usual preventive health care.

c) Investigate participant characteristics that predict participation and success.

d) Conduct a cost analysis to determine the incremental implementation cost to achieve parameters of weight management success (average weight loss, percent achieving levels of weight loss) compared to traditional, clinic-based programs.

3) The following tasks will be necessary to complete the research and technical objectives of this project:

Months 1-6: COMPLETED

1) Hire staff to include the Project Coordinator and Research Associate/Dietary Counselor (There was some initial difficulty in the hiring of project staff. The 2 main positions, Project Coordinator and Research Associate, were appointed in August 2002.)
2) Meet with key personnel to develop coordinated plans for data flow, recruiting, randomization and treatment between San Antonio personnel, Baylor personnel and the consultants

Months 7-12: COMPLETED

1) Order Books and forms to be used as part of research and photocopy assessment forms
2) Develop data entry procedures to include coding and quality assurance measures to protect against outliers and miscoded data
3) Build a web platform and develop 24 weeks of military related weight and exercise content
4) Test each aspect of the website to include ease of use, integrity of data collection for food and exercise diaries, and logistics of providing individualized feedback to diaries and questions
5) Develop Motivational Interviewing telephone script and procedure to include training in motivational interviewing techniques for key project personnel
6) Develop plan with each of the three Health and Wellness Center (HAWC) sites for participant identification, recruitment and assessment

Months 13-19: COMPLETED

1) Begin recruitment and data collection at the three HAWC sites
2) Begin recruiting, orienting and tracking participants
3) Implement MCBT treatment program to include Motivational Interviewing phone contacts, distribution of LEARN manuals, and managing website and individualized weight and exercise feedback
4) Begin data entry and management
5) Hire Administrative Data entry position

Months 20-37*: COMPLETED

1) Begin 6-month follow up assessments for individuals in both conditions (MCBT+UC & UC) – Month 20
2) Begin 12-month follow up assessments for individuals in both conditions (MCBT+UC & UC) – Month 26
3) Recruitment ends at the three HAWC sites in October 2004. Total number of subjects recruited: 451.
4) Continue with orientation, assessment, data management, and treatment related activities

*** Note: Month 37 begins no-cost extension period**

Month 38

1) Complete data collection for 6-month follow-up assessments for individuals in both conditions (MCBT+UC & UC)

Months 43-48

1) Complete data collection for 12-month follow-up assessments for individuals in both conditions (MCBT+UC & UC)
2) Finalize data entry
3) Conduct data analyses
4) Prepare manuscripts
5) Develop treatment package for dissemination to military installations